SLC301, 302, 303
Lamination Core
Installation and User Guide
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CE

INTRODUCTION

Trulife Laminating Cores are used with the Child's Play Energy feet when clearance is insufficient for use with the Ankle Block, but excessive for a Symes Nut. The exterior of the nylon core is ribbed and abrasive for secure adhesion of the laminate. After the core is cut to length, it is laminated directly to the socket. The fabrication is finished conventionally using rigid urethane foam and stockinet. Refer to the chart below for selection and clearance dimensions.

SELECTION

Product Code	Foot Size Range	Max. Patient Weight	Min Clearance (incl. foot)	Max. Clearance (incl. foot)	Required Metric Bolt
SLC301	13-15cm	77 lbs (35kg)	2.2 in (5.6cm)	3.7 in (9.4cm)	M8x80
SLC302	16-18cm	99 lbs (45kg)	2.3 in (5.8cm)	4.1 in (10.4cm)	M8x80
SLC303	19-21cm	144 lbs (65kg)	2.4 in (6.0cm)	4.4 in (11.2cm)	M8x80

INDICATIONS

Lower-limb amputees to build a limb system.

FABRICATION

Recommended fabrication, installation and use procedures must be followed for maximum safety and service life.

⚠ Never modify the laminating core except to cut it to length or to grind off the rotation control rib. Modification can cause failure.

The circular recess on the bottom of the Laminating Core must be placed posterior to the keel centerline as close as possible. Following bench alignment, the Laminating Core can be "tacked" in place with epoxy resin. Before test walking to confirm alignment, secure the Laminating Core to the socket using several layers of fiberglass casting tape as a temporary reinforcement. When satisfactory alignment has been achieved, remove the temporary fiberglass casting tape before applying the definitive lamination.

⚠ Test walking on an unreinforced lamination core can cause failure.

Lamination requires at least two layers of fiberglass. Additional posterior reinforcement is recommended for heavy or high activity level patients.

Lamination must extend to the base of the Laminating Core.

Rotation control can be accomplished by either of two methods. (1) If rotational alignment is satisfactory, the central rib engages with the keel top as the foot mounting bolt is tightened. (2) If additional adjustment is required, grind down the rib. Mold a rib on the Laminating Core by placing a small amount of epoxy resin in the shallow recess. Fillers may be added to the resin to make a paste.

A small amount of wax or clay may be used to fill the keel top groove around the bolt hole. Carefully install the foot and adjust toe-out. Allow the epoxy to cure. The foot may now be removed if desired. If, after a trial period, the toe-out requires adjustment, simply grind the epoxy out of the recess and repeat the rib mounting process.

⚠ Do not contaminate the Laminating Core threads with resin or other substances, including during the lamination process.

INSTALLATION AND USE

The mounting bolt must engage the Lamination Core at least 5/8" (16mm). If the bolt is cut, deburr the cut end to avoid thread damage. Make sure you have a free running thread fit, and the bolt does not bottom out against the socket.

Apply Loctite 242/243 removable thread locking compound to the mounting bolt threads that will engage the lamination core and tighten to 12 ft-lbs (16Nm) using a calibrated torque wrench.

Loctite: When adjusting alignment of bolts or screws that have been assembled with Loctite, the threads of the screw and screw hole should be cleaned free of any Loctite residue with a mild solvent such as alcohol. Then reapply new Loctite; this will ensure that the fasteners are properly tightened to the specified torque value.

⚠ **Warning:**

- Use only bolts and washers supplied by Trulife. Use of unapproved fasteners will void the warranty and can lead to failure.
- Do not contaminate the bolt or thread insert with paint, adhesive, glue or cement.
- Torque settings should be checked periodically. A loosely fastened bolt could lead to failure.
- Never reuse bolts. If you need to reinstall the Lamination Core for any reason, please call Trulife for new bolts.

Trulife

- Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a risk of serious personal injury.

STORAGE AND USE
There are no identified restrictions on the temperature of storage and use.

DISPOSAL
There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION
MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

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LIMITED WARRANTY
Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.